IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC., et al., Plaintiffs, v. LUPIN LTD., et al., Defendants.	C.A. No. 09-037 (RBK) (JS) (CONSOLIDATED)
SHIONOGI INC., et al., Plaintiffs, v. MYLAN INC., et al., Defendants.	C.A. NO. 10-135 (RBK) (JS)

THE LUPIN DEFENDANTS' REPLY BRIEF IN SUPPORT OF MOTION TO STAY OR MODIFY ENFORCEMENT OF THE COURT'S PRELIMINARY INJUNCTION ORDER

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Lupin Ltd. and Lupin Pharmaceuticals USA, Inc. (collectively, "Lupin") respectfully submit this Reply Brief in further support of their Motion for a Stay or Modification Pending Appeal of a Preliminary Injunction (the "Motion"). (D.I. 288.) The Court's injunction enjoins Lupin from infringing patent claims that the PTO did not intend to issue.

I. ERRONEOUS LEGAL CONCLUSIONS AND CLEARLY ERRONEOUS FACTUAL FINDINGS MAKE ISSUANCE OF THE PRELIMINARY INJUNCTION AN "ABUSE OF DISCRETION" THAT JUSTIFIES STAY PENDING APPELLATE REVIEW.

Shionogi's first argument in opposition to a stay or modification of the preliminary injunction characterizes the Motion as a motion to reargue and then asks the Court to deny the Motion because it does not meet the reargument standard of showing new law or facts. (Shionogi Br. at 3-4.) Shionogi's position that a motion for a stay pending appeal should be denied because it is no different from seeking reargument, would in effect repeal FRCP 62(c) in all but the most unusual circumstances. By definition, a party seeking a stay of an injunction pending appeal is asking the judge who granted the injunction to stay his ruling to allow for appellate review. Judges – whether granting or denying the stay – recognize this.[1]

While arguing – incorrectly – that Lupin needs to show new facts or overlooked law to justify a stay pending appeal, Shionogi then ignores the new fact and recent case that were included in Lupin's motion.

This Court held that Lupin "has not filed a petition to vary its label specifications from those of Fortamet®; thus, we continue to operate under the rule of *Abbott Laboratories*, and find

[1] The cases also recognize that absent an expedited appeal, appellate review may be mooted and therefore sometimes condition the injunction on consent to an expedited schedule. *See, e.g., In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation,* C.A. No. 09-2118-SLR, 2011 U.S. Dist. LEXIS 54062 (D. Del. May 20, 2011) (after trial, staying judgment of non-infringement to permit appellate review and enjoining generic sales "if plaintiffs agree to seek an expedited appeal"). Despite Shionogi's opposition to Lupin's request to expedite the appeal, the Federal Circuit granted an expedited briefing schedule that.

that the ANDA specifications of Defendant's product control this Court's infringement inquiry." (Slip Op. at 10.) In response to the Court's comments at the hearing, Lupin approached the FDA and asked permission to vary its label specifications to reflect test results for its own product, rather than Fortamet®, or at least to clarify that the data referred to the brand drug. That permission was denied. (Lupin Br. at 8.) Shionogi does not mention this new fact, and therefore makes no effort to explain why it does not raise a sufficient question about the correctness of the Court's reliance on the label to justify a stay pending an expedited appeal.

Similarly, Shionogi totally ignores *Warner Chilcott Labs. Ireland Ltd. v. Mylan Pharms. Inc.,* C.A. No. 2011-1611, 2011 U.S. App. LEXIS 24602 (Fed. Cir. Dec. 12, 2011) (non-precedential), which illustrates the Federal Circuit's approach and expectations with respect to a trial court's imposition of a preliminary injunction. (*See supra* at 7-9.) Stated simply, *Warner Chilcott* alone warrants granting a stay of the preliminary injunction because, in light of *Warner Chilcott*, appellate reversal is likely.

Shionogi's argument that Lupin does not meet the criteria for a stay of the preliminary injunction relies on style and not substance. Shionogi contends that since Lupin did not argue in that the Court's opinion was an "abuse of discretion," it is conceding that its challenges do not meet the standard for reversal of the grant of the preliminary injunction. Shionogi does not contest that Lupin pointed out several legal errors that it argued were clearly erroneous and would likely result in the appellate court vacating the preliminary injunction. The cases are clear that an error of law is a basis for an appellate conclusion of "abuse of discretion" or reversal of a preliminary injunction, as is a clearly erroneous factual finding. *Titan Tire Corp. v. Case New Holland, Inc.,* 566 F.3d 1372, 1375 (Fed. Cir. 2009); *Xytec Plastics, Inc. v. Ropak Corp.,* C.A. No. 91-1206, 1992 U.S. App. LEXIS 260, at *4-*5 (Fed. Cir. Jan. 8, 1992).

With due respect, Lupin submits that the Court abused its discretion because the preliminary injunction rests on errors of law and clearly erroneous factual findings. The Court applied an erroneous standard of proof in analyzing Lupin's invalidity defense. It erroneously found that a statement on the package insert was a binding admission of infringement. And, as in a recent Federal Circuit case, "[t]he district court abused its discretion in two [additional] ways. The court (1) failed to hold an evidentiary hearing despite acknowledging that the decision turned on disputed factual issues; and (2) did not weigh the evidence or make any findings as to [the generic defendant's] invalidity challenge." *Warner Chilcott*, 2011 U.S. App. LEXIS 24602 at *10.

First, with respect to the burden of proof, even Shionogi agrees that Lupin needed "only raise a substantial question regarding invalidity" (Shionogi Br. at 7), and that Lupin did not need to show invalidity by "clear and convincing evidence" at this stage of the proceedings. Shionogi's argument is that this Court applied the correct standard because the Court cited *Amazon.com, Inc. v. Barnesandnoble.com, Inc.,* 239 F.2d 1343 (Fed. Cir. 2001). (Shionogi Br. at 7.) The Court's decision, however, cited *Amazon.com* only when discussing Shionogi's burden on non-infringement (Slip Op. at 5-6), not Lupin's burden on invalidity later in the opinion. In discussing invalidity, the Court stated twice that it was holding Lupin to a "clear and convincing" burden. (Slip Op. at 11 ("a challenger must prove invalidity by clear and convincing evidence – a high threshold that Lupin cannot meet at this stage") and 12 ("faced with the very steep requirement that the Defendant show clear and convincing evidence of the invalidity of Plaintiff's patent," Lupin had not shown a substantial question)). With due respect, Lupin submits this was clear error. Holding Lupin to a standard of proof that even Shionogi agrees is erroneous makes it likely that the appellate court will find an abuse of discretion and

vacate the injunction. *E.g., Titan Tire,* 566 F.3d at 1375. This error at the least justifies staying the preliminary injunction until appellate review is complete.

Second, Shionogi concedes that the Court based its ruling with respect to infringement on the package insert. (Shionogi Br. at 10.) It does not address the fact that the FDA refused to let Lupin modify the label, despite knowledge that the data did not apply to Lupin's product. It does not address the fact that the FDA refused to let Lupin substitute its data for a single dose administered after breakfast because this was a different test from the multi-dose test on the label. Shionogi also argues that Lupin has raised a new claim construction for the first time on this motion (Shionogi Br. at 11), but that is incorrect. Lupin never contended that a "single dose administered following dinner" where "the drug plasma concentration has not achieved steady state" ('866 Patent, Claim 1 and Col. 7, lines 60-62) was the same thing as multiple doses over four weeks until a steady state drug plasma concentration was reached (as in the test reported on the package insert). Indeed, it is Shionogi that is changing its claim construction position, having earlier argued successfully that "single dose" meant "the <u>total</u> amount of a drug given at one time." (Sept. 7, 2011, Transcript at 135:22-23.) Shionoigi is seeking to lead the Court into further error by equating "single dose" with "multiple doses," a position squarely at odds with the patent specification.

Shionogi also concedes that the Court rejected the sole test of Lupin's product (and rejected the evidence of both the scientist who conducted the test and Lupin's expert witness), by "crediting [Shionogi's] expert testimony that the study was flawed." (Shionogi Br. at 11.) In other words, Shionogi agrees that the Court resolved the factual dispute between experts against Lupin without a hearing. Shionogi did not mention, much less distinguish, the Federal Circuit's discussion in *Warner Chilcott* and the cases cited therein that such conduct by a district court is

reversible error and an abuse of discretion. *Warner Chilcott,* 2011 U.S. App. LEXIS 24602, at *11-*12. In *Warner Chilcott*, the Federal Circuit emphasized that "a district court cannot issue a preliminary injunction that depends upon the resolution of disputed issues of fact unless the court first holds an evidentiary hearing." *Elliott v. Kiesewetter,* 98 F.3d 47, 53 (3d Cir. 1996), quoted in *Warner Chilcott,* 2011 U.S. App. LEXIS 24602, at *11. In *Warner Chilcott*, as here, the disputed issue was "some serious factual disputes between the experts." *Id.* at *12. In *Warner Chilcott,* as here, the Court's resolution of the "factual disputes between the experts" in favor of granting the preliminary injunction without a hearing was an abuse of discretion that will require reversal, and thus justifies a stay pending appeal.

Third, the Court rejected Lupin's argument that the '866 patent was invalid as obvious without explaining its reasoning. It discussed only the irregularities in the issuance of the patent, but did not discuss Lupin's arguments concerning two pieces of prior art (Timmins and Cheng) that, especially after the Supreme Court's ruling in *KSR Int'l v. Teleflex, Inc.,* 550 U.S. 398 (2007), render the patent invalid as obvious. Again, Shionogi does not dispute that Lupin raised this argument, nor does Shionogi dispute that the district court was obliged to consider the obviousness argument. Shionogi's position is that the district court's reference to Lupin's argument that the PTO examiner rejected claim 1's T_{max} range as obvious, meant that it had considered and rejected Lupin's argument that the claim was obvious in light of prior art. (Shionogi Br. at 9.) The Court's reference was in the context of a discussion of the irregularities at the PTO, however. The opinion never mentioned the merits of the argument that the patent was obvious, nor the change in the law since the examiner allowed the patent.

Even if Shionogi were correct that the Court's allusion was intended to indicate its rejection of the substance of the obviousness argument, this statement does not satisfythe Court's

obligation to "find the facts specially and state its conclusions of law separately." Fed. R. Civ. P. 52(a)(1), quoted in *Warner Chilcott*, 2011 U.S. App. LEXIS 24602, at *13. The Federal Circuit is clear that "[s]ufficient factual findings on the material issues are necessary to allow this court to have a basis for meaningful review." *Nutrition 21 v. United States,* 930 F.2d 867, 869 (Fed. Cir. 1991), quoted in *Warner Chilcott*, at *14. At most, this Court made "no more than a passing reference" to Lupin's invalidity challenge and failed to make express findings. *See id.* The Court did not "first . . . weigh the evidence both for and against validity that is available at this preliminary stage in the proceedings." *Titan Tree,* 566 F.3d at 1379, quoted in *Warner Chilcott,* 2011 U.S. App. LEXIS 24602, at *14-15. As in *Warner Chilcott*, this failure is an abuse of discretion that probably will require at least vacatur of the preliminary injunction and a remand for appropriate findings. Thus, a stay of the preliminary injunction to permit appellate review is warranted.

The case on which Shionogi relies does not permit a district court to issue a preliminary injunction by rejecting an obviousness challenge *sub silentio*.[2] (Shionogi Br. at 11.) In *Xytec Plastics, Inc. v. Ropak Corp.,* C.A. No. 91-1206, 1992 U.S. App. LEXIS 260 (Fed. Cir. 1992), defendant's counsel conceded at oral argument that there was enough evidence in the record for the district court to find that plaintiff would likely prevail at trial on the question of infringement. *Id.,* at *5-*6. Lupin's counsel here made no such concession. Moreover, in *Xytec*, the preliminary injunction was granted following a three-day evidentiary hearing. Notably, although the appellate court affirmed the court below, in *Xytec* the preliminary injunction had been stayed pending the appeal. *Id.,* at *4.

[2] Shionogi misstates Lupin's position. Lupin does not complain "about the detail with which the Court addressed Lupin's prior art references in the Opinion" (Shionogi Br. at 10), but about the fact that the Court did not address them at all. They are not even mentioned in the Opinion, and neither is the *KSR* decision.

Shionogi relies on cases where the fact finding and proceedings before the district court actually were "extensive" and where the detailed reasoning behind the court's decision had been set forth on the record. Despite its assertion that there was "extensive" briefing in the instant case (Shionogi Br. at 1, 8), the record before the Court here was no more than an exchange of briefs and an oral argument of less than three hours, with Lupin's presentation truncated to allow the Court to resume a hearing in an ongoing complex criminal matter. This contrasts with the cases on which Shionogi relies, where district courts denied stays pending appeal following trials or summary judgment rulings on extensive records and following multi-day hearings. Shionogi relies extensively on *Sanofi-Aventis U.S. LLC. v. Sandoz, Inc.,* C.A. No. 07-2762, 2009 U.S. Dist. LEXIS 56453 (D.N.J.), where the district judge denied an injunction pending appeal following a summary judgment finding of non-infringement after "extensive briefing," a "lengthy hearing" and a "voluminous record." *Id.,* at *8. Shionogi also neglected to note that the Federal Circuit granted the stay of the injunction pending appeal and, on review, reversed. *Sanofi-Aventis U.S. LLC. V. Sandoz, Inc.,* 345 Fed. Appx. 594, 596, 599 (Fed. Cir. 2009). *See also, e.g., E.I. DuPont De Nemours & Co. v. Phillips Petroleum Co.,* 659 F. Supp. 92 (D. Del. 1987) (following trial) (Shionogi Br. at 9-10); *Tristrata Technology, Inc. v. ICN Pharms., Inc.,* No. 01-150, 2004 U.S. Dist. LEXIS 6557 (D. Del. 2004) (following trial and post-trial motions) (Shionogi Br. at 9-10.)

II. THERE IS NO REASON NOT TO MODIFY THE INJUNCTION IN THE EVENT OF AN AUTHORIZED GENERIC LAUNCH

District courts have agreed with Lupin's position here that the equities usually do not support enjoining generic marketing while allowing an authorized generic to move into the market. Shionogi has not stated that there will not be authorized generic competition, nor has it provided any information about its or Watson's plans. Shionogi has not disagreed with the

statements that it cannot control whether Watson launches an authorized generic product, nor has Shionogi disputed that it will suffer the same allegedly irreparable injuries if it must compete with an authorized generic as it feared from competition with Lupin's generic product. Shionogi has given no reason why this Court should not modify the injunction to provide that it will be lifted if another generic Fortamet® product enters the market. Shionogi's entire one-paragraph argument is just that the possibility of authorized generic competition was raised on the motion for a preliminary injunction. *See, e.g., Ortho McNeil Pharm., Inc., v. Barr Labs., Inc.,* C.A. No. 03-4678, 2009 U.S. Dist. LEXIS 62721 at 31 (D.N.J. July 21, 2009) (granting preliminary injunction "subject to the condition that Ortho agrees to refrain from offering a generic TCL product for sale during the pendency of the injunction."); *In re Cyclobenzaprine,* 2011 U.S. Dist. LEXIS 54062 at *10-11 (granting injunction pending appeal of trial finding of non-infringement if authorized generic was removed from the market).

III. CONCLUSION

Lupin respectfully urges the Court to recognize the possibility that it has been led into error that may warrant appellate reversal, and to stay or modify the preliminary injunction to maintain the status quo until that appellate review can be accomplished.

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